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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,169	04/06/2004	John L. Faul	S03-013/US	7036

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EXAMINER	
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ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/820,169	FAUL ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/961,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because, despite some variance in claim terminology, each substantive element or method step contained in the instant claims are present in the claims of the copending case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

4. Misnumbered claim 18 on page 6 has been renumbered 28.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3-8, 10, 11, 13, 15-21, 27-30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,315,752 to DiMatteo in view of US 5,662,711 to Douglas.

In the specification and figures, DiMatteo discloses an apparatus and method for creating a bypass shunt between an artery and a vein. With regard to claims 1, 4, 5, 10, 13, 18, 20, 27, 32, the device comprises a tubular bypass graft 100 that establishes fluid connection between an artery 110 and a vein 120 (see FIG 1, column 3, lines 18-40). Arterial flow is diverted through the bypass device to the venous flow, thereby bypassing peripheral microcirculation, as claimed by applicant (see column 3, lines 14-27).

DiMatteo is silent as to the flow rate of fluid through the shunt, but discloses that the length of the tube may be varied to establish desired flow characteristics such as rate (see column 4, lines 40-51). Douglas discloses a vessel-to-vessel shunt (which may be deployed between an artery and *another systemic vessel*, see column 2, lines 11-13) that uses an inflatable bladder to vary the cross-section of the shunt to control flow rate of fluid through the shunt. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add an inflatable occluder as disclosed by Douglas to the arteriovenous shunt disclosed by DiMatteo in order to adjust the flow rate through the shunt, as taught by Douglas.

With regard to applicant's recitation that creation of a fistula increases cardiac output, decreases systemic vascular resistance in a patient, or increases PO_2, it is the position of the examiner that the fistula or shunt disclosed by DiMatteo necessarily creates such an effect, since the steps of the method claimed by applicant are identical to the steps disclosed by DiMatteo.

It has been held that where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. In re *Swinehart*, 439 F2d 210 (169 USPQ 226 (CCPA 1971).

In the instant case, Examiner sees no step or limitation that distinguishes the instantly claimed method over that of the prior art, and believes that the DiMatteo method creates the beneficial cardiovascular effects claimed by applicant. In the absence of any evidence that applicant's method produces an effect not produced by the prior art, the invention is unpatentable over the prior art of record.

With regard to claim 3, DiMatteo discloses that the bypass device and implantation procedure may be used to avoid damaged or diseased blood vessels, thereby treating a circulatory condition (see column 1, lines 10-20).

With regard to claims 6-8, 15-17, 29, the prior art is silent as to the dimensions of the disclosed shunt. However, it has been held that where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device

and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). In the instant case, applicant has not set forth any criticality to the claimed dimensions, and it appears that the shunt suggested by the prior art would perform in the same manner as the dimensioned device claimed by applicant. Therefore, the claimed dimensions are patentably indistinct from the prior art.

With regard to claims 11 and 21, Douglas discloses that the controller 120 is capable of controlling the restriction of the shunt 100 via bladder 130, which adjusts the cross-sectional area of the shunt (see column 4, lines 19-59). Douglas does not disclose that the controller controls the bladder as a function of the pressure difference across the shunt. However, Applicant merely claims that the device is *capable* of performing such a procedure as a function of pressure. Douglas discloses that the shunt and restrictor may be manually controlled or controlled based on signals other than those from oximeter 114 (see column 5, lines 35-50). Therefore, Douglas discloses that the device is *capable* of operating as claimed by applicant (i.e., in response to rate or pressure), meeting the limitations of the claim.

With regard to renumbered claim 28 and claim 30 drawn to adjusting the flow rate of fluid through the shunt and the size of the shunt, Douglas specifically discloses that the shunt 100 includes an adjustable restrictor or valve 110 that is used to adjust the flow rate of blood through the shunt to control the oxygen saturation level of the blood flowing through the shunt (see column 2, lines 11-28, column 4, lines 19-25). The flow rate is controlled by adjusting the cross-sectional area of the shunt via bladder 113

(see column 2, lines 29-38). Douglas specifically teaches that the rate of flow through the shunt is a result-effective variable that may be used to achieve the desired oxygen saturation level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the rate of flow through the Douglas shunt to the rate claimed by applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP 2144.05. In this case, a person of ordinary skill in the art would reasonably obtain applicant's flow rate by optimizing the flow rate in the manner taught by Douglas (column 2, lines 29-38).

With regard to claim 19, Douglas discloses that the restrictor 110 in shunt 100 may be selectively activated by controller 120 to control fluid flow rate through the shunt based on signals from sensor 114 that monitors oxygen saturation, meeting the limitations of the claim (see column 2, lines 11-28, column 4, lines 19-25). With regard to applicant's limitations drawn to the operation of the sensor, such a limitation is considered by the Examiner to be a functional recitation of the operation of the claimed sensor. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Douglas discloses that the device comprises a sensor 114, but does not disclose that the sensor is "to sense" rate or pressure. However, Douglas discloses that the shunt and restrictor may be manually controlled or controlled based on signals other than those from oximeter 114 (see column 5, lines 35-50). Therefore, Douglas discloses

that the device is *capable* of operating as claimed by applicant (i.e., in response to rate or pressure), meeting the limitations of the claim.

7. Claims 2, 12, 14, 23-26, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,315,752 to DiMatteo in view of US 5,662,711 to Douglas, further in view of US 6,485,513 to Fan.

In the specification and figures, DiMatteo and Douglas suggest the method claimed by applicant but do not disclose that the shunt is implanted in the femoral or axillary artery and vein or the method of implantation .

Fan discloses a method for creating an arteriovenous bypass graft through an opening in the skin (see column 4, lines 39-40) or an intravascular procedure (see column 3, lines 38-55). The device may be connected between a systemic artery and vein such as the femoral artery and vein (which are distal, or father from the heart than the renal vessels) or axillary artery and vein (which are proximal, or nearer to the heart, than the renal vessels) (see column 3, lines 55-60). Therefore, it would have been obvious to one having ordinary skill in the art to place the shunt suggested by DiMatteo and Douglas in the location disclosed by Fan with the intravascular technique disclosed by Fan, since the references reasonably suggest that an intravascularly placed shunt in the femoral or axillary vessels is known in the art, and such a combination would have been obvious to one of ordinary skill in the art.

8. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,315,752 to DiMatteo in view of US 5,662,711 to Douglas, further in view of US 5,004,461 to Wilson.

In the specification and figures, the prior art suggests the device substantially as claimed by applicant (see rejection above) with the exception of a coating to prevent clot formation. It is well-known in the art of implantable medical devices to provide an antithrombotic agent to the implantable device in order to prevent clot formation, as disclosed by Wilson (see column 2, lines 5-43). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shunt suggested by the prior art with an antithrombotic coating, as disclosed by Wilson, to prevent clot formation, as taught by Wilson.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,315,752 to DiMatteo in view of US 5,662,711 to Douglas, further in view of US 6,632,243 to Zadno-Azizi et al

In the specification and figures, DiMatteo and Douglas suggest the method claimed by applicant (including a control valve 110 disclosed by Douglas) but do not disclose that the shunt controlled via a one-way valve with the claimed operating pressure. Zadno-Azizi discloses a valve for use in a duct or passageway (which may comprise a shunt) to control body fluid flow. The valve is capable of providing one-awy flow and has a cardiovascular opening pressure of 0.005psi to 1.0 psi, which is within applicant's claimed range (see column 1, lines 45-56, column 2, lines 60-64). Therefore,

it would have been obvious to one having ordinary skill in the art at the time of invention to replace the valve disclosed by Douglas with the valve disclosed by Zadno-Azizi in order to provide appropriate cardiovascular opening pressures, as taught by Zadno-Azizi.

Response to Arguments

10. Applicant's amendment and arguments filed 27 March 2007 with respect to the 35 USC 102 and 103 rejections of the pending claims have been entered and fully considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments, with respect to the 35 USC 101 and 112 rejections have been fully considered and are persuasive. The rejections of the pending claims under 35 USC 101 and 112 has been withdrawn.

12. With regard to the provisional double patenting rejection, Examiner appreciates that this case is junior to 10/961,731. However, MPEP 804(I)(B) provides that the provisional double patenting rejection should continue to be made by the Examiner in each application as long as there are conflicting claims in more than one application unless the provisional double patenting rejection is the only rejection remaining in at least one of the applications. Accordingly, the rejection is repeated herein.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
4 June 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER